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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,745	06/27/2003	Peter Gluckman	704652-9001	5345

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,745	GLUCKMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040213*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The maintenance fees due at 3.5 years and 7.5 years after the issue date of U.S. Patent No. 5,714,460 have been paid, and therefore the reissue procedures are available for this patent.

This reissue application was filed within two months of the mailing date of the final judgment of interference 104,553, and therefore the reissue procedures are available for this patent.

2. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172*(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b).

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

Papers attempting to establish the consent of assignee to the reissue were filed on November 1, 2004. However, the papers are contradictory. One paper, signed by Timothy R. Schwartz, PhD., states that Genentech, Inc. is the owner of the entire right, title and interest in and to U.S. Patent No. 5,714,460. A second paper, signed by Paulina Lucrynska (sp.?), states that NeuronZ Limited is the owner of the entire right, title and interest in and to U.S. Patent No. 5,714,460. Two separate legal entitles cannot each be the owner of the entire right, title and interest in a single U.S. patent. Further, according to the assignment records of the U.S. Patent and Trademark Office, NeuronZ LTD is the only assignee of record for U.S. Patent No. 5,714,460. Correction is required.

3. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,583,114 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

4. This reissue application was filed on June 27, 2003 with a set of forty-eight new claims. However, these claims were not numbered beginning with the number following the highest numbered patent claim (see 37 CFR 1.173(e)). Accordingly, these claims have been re-numbered as 16 through 63, respectively. Any future reference to these claims will use their re-numbered claim numbers. In the response to this Office action, Applicants must submit a new set of claims in appropriate amendment form showing the re-numbered claim numbers and showing corrected claim dependencies.

This reissue application was not filed with any instruction to cancel claims 1-15 of the patent. Accordingly, claims 1-63 are pending in this reissue application.

5. It should be noted that there is no claim for priority under 35 U.S.C. 119(a)-(d) present in this reissue application. A claim for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application, even though such a claim was previously made in the application for the original patent to be reissued. See MPEP 1417, which

also outlines the procedures for claiming priority under 35 U.S.C. 119(a)-(d) in a reissue application.

6. In the title of the invention as set forth at column 1, line 1, of the specification, "IGF-1" is misspelled. Correction is required.

7. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

Claims 1-63 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175. The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

> § 41.127 Judgment.
> (a) *Effect within Office*—(1) *Estoppel.* A judgment disposes of all issues that were, or by motion could have properly been, raised and decided. A losing party who could have properly moved for relief on an issue, but did not so move, may not take action in the Office after the judgment that is inconsistent with that party's failure to move, except that a losing party shall not be estopped with respect to any contested subject matter for which that party was awarded a favorable judgment.

9. Claims 1-15 are rejected under 35 U.S.C. 102(g) as being estopped on the merits by final judgment in Interference No. 104,553. Claims 1-15 in the instant application are identical to claims 1-15 of U.S. Patent No. 5,714,460, one of the parties in the interference. In the final judgment, it was held that Gluckman is not entitled to a patent containing claims 1-15 of U.S. Patent No. 5,714,460, which correspond to Count 1 of the interference. Accordingly, Applicants are estopped from asserting these claims in this reissue application. See also 37 CFR 41.127(a) and MPEP 2308.03, Example 1 (Rev. 4, October 2005).

10. Claims 16-18, 23-30, 35-42, 47-54, and 59-63 are rejected under 35 U.S.C. 102(g) as being estopped on the merits by final judgment in Interference No. 104,533. Claims 16, 28, 40, and 52 are clearly anticipated by that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. In this section of the count, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. With respect to instant claims 17, 23, 29, 35, 41, 47, 53, and 59, these claims recite the same limitation as is recited in claims 3 and 4 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 27-29 of the Decision On Motions). Accordingly, claims 17, 23, 29, 35, 41, 47, 53, and 59 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. With respect to instant claims 18, 30, 42, and 54, these claims recite the same limitation as is recited in claim 2 of the '460 patent, which was designated as corresponding to the count. Gluckman did not file any motion in the interference contesting the designation of this claim as corresponding to the count. Accordingly, claims 18, 30, 42, and 54 are deemed obvious over that section of the count which corresponds to

claim 1 of U.S. Patent No. 5,714,460. With respect to claims 24-27, 36-39, 48-51, and 60-63, these claims recite the same or broader limitations as are recited in claims 7-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Accordingly, claims 24-27, 36-39, 48-51, and 60-63 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over (or even anticipated by) the lost count.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 90/14838. The WO Patent

Application '838 teaches treating head or spinal cord injuries, and treating diseases including stroke and Parkinson's disease, by administering IGF-I or a functional derivative thereof, or by administering IGF-II or a functional derivative thereof. The active agents are administered parenterally, including intracranially and intraspinally. See, e.g., page 21, lines 1-11, and claim 77. Head and spinal cord injuries are species of traumatic injuries. A stroke is a species of a hypoxic injury. Parkinson's disease is a species of a chronic injury and of a degenerative injury. IGF-I functional derivatives, IGF-II, and IGF-II functional derivatives are biological analogs of IGF-I. Because the same active agents are being administered to the same mammals according to the same method steps in order to treat the same CNS injuries, inherently damaged glial cells and damaged non-cholinergic cells will be treated in the method of the WO Patent Application '838 to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the WO Patent Application '838 and Applicants claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of the WO Patent Application '838.

With respect to the inherency rejection, note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed method on the basis of inherency. See Ex parte Novitski, 26 USPQ2d 1389, 1391 (POBA 1993); In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CAFC 2002); and more generally MPEP 2112. Note also that the instant claims do not exclude from their scope the possibility that neuronal cells and/or cholinergic cells are treated at the same time that glial cells and/or non-cholinergic cells are treated.

See also the Decision On Motions, pages 39-43, in which it was held that all claims of the '460 patent which corresponded to the count were unpatentable over the prior art.

13. Claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 90/14838 as applied against claims 16-18, 23-25, 27-30, 35-37, 39-42, 47-49, 51-54, 59-61, and 63 above, and further in view of the Lesniak et al article (Endocrinology, Vol. 123, pages 2089-2099), the Knusel et al article (J. Neuroscience, Vol. 10, pages 558-570), or the Kiess et al article (Endocrinology, Vol. 124, pages 1727-1736). The WO Patent Application '838 does not teach that its treatment with IGF-I or its functional derivatives, or with IGF-II or its functional derivatives, has any effect on glial cells or non-cholinergic cells. The Lesniak et al article (see, e.g., page 2089, column 2, last paragraph) teaches that IGF-I receptors are widely distributed in the brain. The Knusel et al article (see, e.g., the Abstract and page 566, paragraph bridging columns 1 and 2) teaches that IGF-I receptors are heterogeneously distributed in the adult mammalian brain, and that IGF-I stimulates cholinergic and dopaminergic, i.e. non-cholinergic, neurons in culture. Accordingly, IGF-I receptors would have been expected to be present in cholinergic and non-cholinergic neurons. The Kiess et al article (see, e.g., the Abstract) specifically teaches that IGF-I receptors are present in glial cells. Accordingly, when head or spinal cord injuries or diseases are treated by administering IGF-I or its functional derivatives or IGF-II or its functional derivatives as is taught by the WO Patent Application '838, it would have been expected that glia cells and non-cholinergic cells expressing IGF-I receptors would be present as taught by the Lesniak et al article, the Knusel et a article, and the Kiess et al article, and the cells would have been expected to respond to the administered IGF-I. The Lesniak et al article, the Knusel et al article, and the

Kiess et al article are further evidence that Applicants' claimed method is inherent in the method of the WO Patent Application '838.

14. Claims 16-21, 28-33, 40-45, and 52-57 are rejected under 35 U.S.C. 102(a) as being anticipated by the Gluckman et al article (Biochem. Biophys. Res. Comm. vol. 182, pages 593-599). The Gluckman et al article teaches subjecting rats to inhalational hypoxia, i.e. asphyxia, and then administering IGF-1 to the injured hemisphere. Neuronal loss is reduced, especially in the lateral cortex and in the dentate gyrus. See, e.g., page 595, first full and last paragraphs. In view of the identity in mammal, injury, therapeutic agent, and treatment steps between the Gluckman et al article and Applicants' claimed method, inherently glial cells and non-cholinergic cells will be damaged and treated in the method of the Gluckman et al article to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between method of the Gluckman et al article and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than that of the Gluckman et al article.

With respect to the inherency rejection, note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed method on the basis of inherency. See Ex parte Novitski, 26 USPQ2d 1389, 1391 (POBA 1993); In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CAFC 2002); and more generally MPEP 2112. Note also that the instant claims do not exclude from their scope the possibility that neuronal cells and/or cholinergic cells are treated at the same time that glial cells and/or non-cholinergic cells are treated.

With respect to claims 28-33 and 52-57, this rejection assumes that IGF-1 is "a biological analog of IGF-1". Applicants define "biological analogue" at column 5, lines 22-27, of the specification as meaning "compounds which exert a similar biological effect to IGF-1". IGF-1 exerts a similar biological effect to IGF-1, and there is no indication that Applicants intended to exclude IGF-1 from being considered as a biological analogue.

Should Applicants attempt to antedate the Gluckman et al article by perfecting a claim for priority under 35 U.S.C. 119(a)-(d) (see also section 5 above), Applicants should explain why any claims rejected over the Gluckman et al article would be entitled to the benefit of the filing date of the New Zealand foreign priority application. In particular, it is noted that the New Zealand foreign priority application does not explicitly recite that glial cells or non-cholinergic cells are damaged and then treated.

15. Claims 28, 36-38, 52, and 60-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al (U.S. Patent No. 5,219,837). Cohen et al teach treating diseases characterized by loss of myelin destruction, such as multiple sclerosis, comprising administering various synthetic peptides which include myelin formation by oligodendrocytes. See e.g., the Abstract; column 1, line 52 - column 2, line 33; and column 5, lines 35-59. The synthetic peptides of Cohen et al are deemed to constitute biological analogs of IGF-1, because the synthetic peptides have the biological effects of stimulating oligodendrocytes to produce myelin and of being useful in treating multiple sclerosis. Note that Applicants' definition of "biological analog" at column 5, lines 22-27, does not recite which biological effect or effects of IGF-1 a biological analog must exhibit. In view of the identity in mammal, injury, therapeutic agent, and treatment steps between Cohen et al and Applicants' claimed method, inherently glial cells and non-cholinergic

cells will be damaged and treated in the method of Cohen et al to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between method of the Cohen et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than that of the Cohen et al.

Oligodendrocytes are a species of glial cells. Because oligodendrocytes are non-neuronal cells, they are necessarily non-cholinergic cells (see the Decision On Motions at [10]).

With respect to the inherency rejection, note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed method on the basis of inherency. See Ex parte Novitski, 26 USPQ2d 1389, 1391 (POBA 1993); In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CAFC 2002); and more generally MPEP 2112. Note also that the instant claims do not exclude from their scope the possibility that neuronal cells and/or cholinergic cells are treated at the same time that glial cells and/or non-cholinergic cells are treated.

16. Claims 22, 34, 46, and 58 are novel and unobvious over the prior art of record or any combination thereof. The prior art of record does not teach or suggest treating glial cells or non-cholinergic cells damaged by injury to the hippocampus, wherein the treatment comprises in vivo administration of IGF-1 or a biological analog thereof.

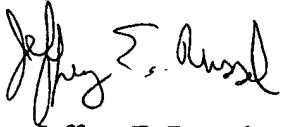
The WO Patent Application 90/14838 is not applied against instant claims 19-22, 26, 31-34, 38, 43-46, 50, 55-58, and 62. The WO Patent Application '838 does not teach, inherently or explicitly, treating injuries caused by asphyxia or multiple sclerosis, or treating injuries to the cortex, the dentate gyrus, or the hippocampus. The specific injuries and diseases taught by the WO Patent Application '838 do not inherently result in injuries to glial cells or non-cholinergic

cells present in the cortex, the dentate gyrus, or the hippocampus. Further, because the WO Patent Application '838 does not describe IGF-I or its functional derivatives or IGF-II or its functional derivatives as having any effect on glial cells or non-cholinergic cells, the WO Patent Application '838 does not provide any motivation to treat glial cells or non-cholinergic cells which are damaged as a result of injuries caused by asphyxia or multiple sclerosis or as a result of injuries to the cortex, the dentate gyrus, or the hippocampus.

U.S. Patent No. 5,861,373 is cited as art of interest, it being one of the patents involved in Interference No. 104,553. However, in the final judgment, it was held that Gluckman was not entitled to the sole claim present in the '373 patent. Further, the '373 patent issued at a later date than the patent upon which this reissue application is based. Accordingly, an obviousness-type double patenting rejection in this application over the '373 patent will not be made because the policy concerns underlying such a rejection (possibility of disparate ownership of obvious variations of the same invention, and undue extension of the patent monopoly) do not exist.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
March 31, 2006